Exhibit 6
(Filed Under Seal)

Expert Report

Debra Tinlin v. CR Bard Inc.

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DEPOSITION EXHIBIT
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1. Introduction and Qualifications

My name is Darren R. Hurst. I am a full-time physician and fellowship-trained vascular and interventional radiologist. The discipline of vascular and interventional radiology involves the diagnosis, treatment, and management of medical diseases and health conditions through imaging and targeted, image-guided, minimally invasive surgical procedures. The procedures I perform involve the introduction of medical devices into the human body under image guidance such as ultrasound, CT, and fluoroscopy. Often, this involves the use of needles, guidewires, catheters, balloons, stents, drains, and other medical devices. My education, training, and experience are detailed in my CV which is in appendix A of this report. My practice is located in Edgewood, Kentucky and serves the Greater Cincinnati, Ohio area. I am familiar with the issues, subject matter, and topics involved in this litigation. I have personal experience with the use of both permanent and retrievable inferior vena cava ("IVC") filters for the prevention of pulmonary embolism. As part of my practice, I regularly implant and retrieve IVC filters. I am familiar with the relevant medical literature that addresses the issues concerning IVC filters, including but not limited to the indications and contraindications for use, placement, complications, and risks and benefits of the devices. I am also familiar with and have utilized multiple different types of filter devices including the Bard Simon Nitinol Filter® ("SNF"), Recovery Filter®, G2 Filter®, G2X Filter®, Eclipse®, and Denali Filter®. This experience, in combination with my education and training in the field of medicine and specifically the field of Vascular and Interventional Radiology, has formed the basis for my opinions rendered in this litigation.

2. Case Specific Materials Reviewed
    a. Medical Records:
        i. Reviewed all medical records supplied from 5/7/05 to 12/16/15.

b. Imaging Reviewed:
   i. 5/4/05 CTA Chest
      1. IVC measures 2.5 x 1.5 cm.
      2. Bilateral lower lobe pulmonary embolism.
   ii. 5/7/05 IVC filter placement
      1. Tip at inferior endplate of L1.
      2. No marker catheter utilized. Unable to measure IVC.
      3. No significant tilt.
   iii. 5/8/05 CT Abdomen and Pelvis
      1. IVC measures 23 x 15 mm at level just above IVC filter
      2. 18 degree tilt now present. Tip of filter against anterior wall of IVC with caudal migration of 9 mm.
      3. 12 o'clock arm grade 3 penetration of IVC with interaction with the posterior wall of the duodenum.
      4. 2 o'clock arm grade 2 penetration of the IVC in to the retroperitoneum.
      5. 4 o'clock arm grade 2 penetration of the IVC into the retroperitoneum.
      6. 6 o'clock arm grade 3 penetration of the IVC into the L3/4 intervertebral disc.
      7. 7 o'clock arm grade 2 penetration of the IVC into the retroperitoneum.
      8. 10 o'clock arm grade 3 penetration of the IVC with interaction with the posterior wall of the duodenum.
      9. 1 o'clock leg within IVC.
      10. 3 o'clock leg within IVC.
      11. 4 o'clock leg with grade 3 penetration of the IVC and interaction with the superior endplate of the L3 vertebral body.
      12. 6 o'clock leg with grade 3 penetration of the IVC and interaction with the superior endplate of the L3 vertebral body.
      13. 7 o'clock leg within IVC.
      14. 10 o'clock leg within IVC.
   iv. 5/9/05 CT Lumbar spine
      1. IVC measures 23 x 15 mm at level of IVC filter.
      2. 18 degree tilt present.
      3. Tip of filter with caudal migration of 9 mm at superior endplate of L2.

4. 12 o'clock arm grade 3 penetration of IVC with interaction with the posterior wall of the duodenum.
5. 2 o'clock arm grade 2 penetration of the IVC in to the retroperitoneum.
6. 4 o'clock arm grade 2 penetration of the IVC into the retroperitoneum.
7. 6 o'clock arm grade 3 penetration of the IVC into the L3/4 intervertebral disc.
8. 7 o'clock arm grade 2 penetration of the IVC into the retroperitoneum.
9. 10 o'clock arm grade 3 penetration of the IVC with interaction with the posterior wall of the duodenum.
10. 1 o'clock leg within IVC.
11. 3 o'clock leg within IVC.
12. 4 o'clock leg with grade 3 penetration of the IVC and interaction with the superior endplate of the L3 vertebral body.
13. 6 o'clock leg with grade 3 penetration of the IVC and interaction with the superior endplate of the L3 vertebral body.
14. 7 o'clock leg within IVC.
15. 10 o'clock leg within IVC.

v. 5/26/05 CXR Two views
   1. Negative. Filter not visualized.

vi. 6/28/05 CXR Two views
   1. Negative. Filter not visualized.

vii. 10/31/05 CXR
   1. New, fractured, embolized arm #1 in right ventricle.

viii. 1/27/06 Thoracic spine XR
   1. Fractured, embolized arm #1 in right ventricle.

ix. 1/27/06 Lumbar spine XR
   1. Four arms definitely visualized. Difficult to determine whether a fifth arm is attached to the filter.
   2. Six legs visualized.
   3. Filter tip at superior endplate of L2 unchanged in position.

x. 7/27/06 CT Chest with contrast
   1. Re-demonstration of embolized arm #1 in inferior right ventricle.

2. New fractured, embolized arm #2 in inferior right ventricle.
3. Filter not visualized on CT.

xi. 9/26/06 CXR two views
1. Embolized arm #1 visualized on PA view in RV.
2. Embolized arm #2 visualized on lateral view in RV.

xii. 10/27/06 CT Chest with contrast.
1. Embolized arms #1 and #2 visualized in RV.

xiii. 2/23/07 CXR
1. Negative. Fractured arms not visualized.
2. Filter not visualized.

xiv. 6/11/07 AXR
1. Filter with mild additional caudal migration now at superior margin of L2 pedicle. 1.2 cm from original location.
2. Additional splaying of right arm of filter.
3. Four arms and six legs visualized on filter.

xv. 4/15/08 CXR
1. Demonstration of newly fractured and embolized arm #3 overlying RUL in the RUL apical pulmonary artery on AP view.

xvi. 4/15/08 CT Chest without contrast.
1. Two fractured, embolized arms of the filter are demonstrated within the apex of the right ventricle (embolized arm #1 and #2). The more posterior arm is now likely partially embedded in the interventricular septum.
2. Embolized arm #3 to RUL pulmonary artery demonstrated. Difficult to visualize.

xvii. 2/3/12 AXR
1. Filter tip at inferior margin of pedicle 2.8 cm caudal migration.
2. 6 legs and 2 arms present on filter. There has been additional fracture and embolization/migration of one more arm. Fractured, embolized arms #1, #2, and #3 not visible on this exam.
3. New RLL pulmonary artery embolized arm #4 visualized on AP view.

xviii. 2/7/12 CT Abdomen and Pelvis with contrast.

1. Re-demonstration of two fractured, embolized arms (#1 and #2) in the right ventricle.
2. Fractured arm #4 in the right lower lobe posterior segment pulmonary artery.
3. 3 o'clock arm grade 2 penetration of the IVC into the retroperitoneum anterior to the L3 vertebral body.
4. 7 o'clock arm with grade 2 penetration of the IVC into the posterior retroperitoneum.
5. 12 o'clock leg with grade 2 penetration of the IVC into the retroperitoneum
6. 3 o'clock leg with grade 2 penetration into the retroperitoneum.
7. 4 o'clock leg with grade 3 penetration into the L3 vertebral body 1.2 cm with sclerotic reaction and osteophyte.
8. 7 o'clock leg with grade 3 penetration and interaction with L3/4 disk.
9. 8 o'clock leg with grade 2 penetration of IVC.
10. 11 o'clock leg in the lumen of the IVC
11. Two arms present on filter. Two arms in the cavity of the right ventricle (#1 and #2). One arm in right lower lobe pulmonary artery (#4). One arm located in RUL apical pulmonary artery (#3) not included on this study. One arm not visualized on study (#5). I suspect it is already within the right middle lobe pulmonary artery, but, it is not well seen on this study.

xix. 6/10/13 CXR

1. Pulmonary edema. Filter not visualized.
2. Embolized arm #1 seen on AP view.

xx. 6/10/13 AXR

1. Filter tip at inferior margin of right L2 pedicle.
2. 13 degree tilt.
3. Unable to adequately visualize filter to evaluate arms and legs.

xxi. 6/10/13 CTA Chest.
   1. Embolized filter arm #5 in anterior segment right middle lobe pulmonary artery seen on sagittal view.
   2. Embolized filter arm #4 in right lower lobe pulmonary artery.
   3. Difficult to visualize RUL apical segment embolized arm #3 on this study.
   4. One of the intra-cardiac embolized filter arms (#1) has acutely perforated the anterior apical wall of the right ventricle, which has resulted in a large pericardial effusion with high attenuation consistent with acute hemopericardium.
   5. The second intra-cardiac embolized filter arm (#2) has perforated the interventricular septum and is partially in the right ventricle and partially in the left ventricle.

xxii. 6/11/13 – 6/17/13 Multiple CXR
   1. Continued pulmonary edema. Unable to visualize embolized arms.

xxiii. 6/12/13 AXR
   1. Filter unchanged in position. Still unable to visualize arms and legs.

xxiv. 6/14/13 AXR.
   1. Filter at L2 pedicle. Unchanged in position. Unable to visualize arms and legs.

xxv. 7/3/13, 7/29/13, 7/30/13, 8/1/13, 8/2/13, 8/3/13 Multiple CXR single view portables.
   1. RML fractured, embolized arm #5 visualized. No change over multiple exams.
   2. RLL fractured, embolized arm #4 not visualized on AP portable views.
   3. RUL fractured, embolized arm #3 visualized on AP views.

xxvi. 8/6/13 CXR two view.
   1. Fractured, embolized arm #4 in the right lower lobe posterior segment pulmonary artery on lateral view.
   2. Fractured, embolized arm #5 in the right middle lobe anterior segment pulmonary artery on the lateral view.
   3. Fractured, embolized arm #3 in the right upper lobe apical pulmonary artery on AP view.

xxvii. 8/7/13 CT Chest without contrast.

1. Median sternotomy.
2. Mild pericardial thickening/small effusion.
3. Evidence of prior repair of right ventricle apex.
4. No fragments identified in right ventricle or heart.
5. Embolized arm #4 in RLL posterior segment pulmonary artery.
6. Embolized arm #5 in RML anterior segment pulmonary artery.
7. Embolized arm #3 in RUL apical segment pulmonary artery.
8. 9 degree tilt of filter.
9. 8 o'clock arm of filter with grade 2 penetration of IVC into retroperitoneum.
10. 2 o'clock leg with grade 3 penetration of duodenum.
11. 3 o'clock leg with grade 3 interaction with lateral wall of aorta.
12. 5 o'clock leg with grade 3 penetration of the L3 vertebral body with leg 1 cm into the body with resultant sclerotic reaction.
13. 7 o'clock leg with grade 3 interaction with the L3/L4 disc.
14. 8 o'clock leg with grade 2 penetration into the retroperitoneum.
15. 10 o'clock leg within IVC lumen.
16. On the current examination, there is only one remaining arm attached to the filter. Three embolized arms (#3, #4, and #5) are in the pulmonary arteries as described above. One embolized arm was retrieved during open heart surgery (#1). The second arm (#2) within the right ventricle was never localized or retrieved and is not visualized on the CT examinations.

xxviii. 8/22/13 CXR

1. Fractured, embolized arm #3 demonstrated overlying RUL of lung in RUL pulmonary artery.

xxix. 8/22/13 CTA Chest.

1. Stable appearance of cardiac structures.
2. No new embolized components.
3. No change in position of embolized arms #3, #4, and #5 in the pulmonary arteries.

xxx. 10/23/13 CT Chest without contrast.

1. Resolution of pericardial effusion. Mild pericardial thickening.
2. No change in position of embolized arms #3, #4, and #5 in the pulmonary arteries.

xxxi. 11/11/13 CXR
1. No change in position of embolized arms #3, #4, and #5.

xxxii. 11/11/13 CT Chest without contrast.
1. No change in position of embolized arms #3, #4, and #5.

xxxiii. 3/12/14 CT Chest without contrast.
1. No change in position of embolized arms #3, #4, and #5.

xxxiv. 8/5/14 CT Chest with contrast.
1. No change in position of embolized arms #3, #4, and #5.

xxxv. 8/19/15 CT Abdomen and Pelvis with contrast.
1. No change in position of embolized arms #4 and #5 in pulmonary arteries. Embolized arm #3 in the RUL is not included on this study and is not visualized.
2. No new embolized components.
3. No change in position or appearance of filter. Still with a single retained arm, and six legs with continued grade 3 penetrations/interactions as described above of the aorta, duodenum, L3/L4 disc, and L3 vertebral body.
4. New midline incisional hernia upper abdomen/lower chest.

xxxvi. 12/3/15 CXR
1. Embolized arm #3 demonstrated overlying right upper lobe of lung in RUL pulmonary artery.
2. Embolized arm #4 in right lower lobe pulmonary artery unchanged.

xxxvii. 12/16/15 Clavicle XR
1. Fractured, embolized arm #3 in right upper lobe pulmonary artery.

xxxviii. 10/18/16 CT Chest without contrast.
1. No change in position of embolized arms #3, #4, and #5 in pulmonary arteries.
2. No new embolized components.
3. Filter not visualized on examination.
4. Interval mesh repair of midline hernia.

xxxix. 2/26/16 Right shoulder XR
1. Embolized arm #3 re-demonstrated overlying right upper lobe of lung.

c. IFUs:
    i. Eclipse Filter
    ii. Bard G2 and G2x Filter
    iii. Bard Recovery Filter
    iv. Bard Simon Nitinol Filter
d. Bard Materials Reviewed:
    i. Internal Documents: See appendix.
    ii. Depositions: See appendix.
e. Medical Literature:
    i. See appendix.
f. Expert Reports
    i. Drs. Kinney, Roberts, and Kalva, Mark Eisenberg, M. D. I have reviewed these reports, I agree with them, and I adopt the opinions and bases for those opinions set forth therein.

3. Case Summary:
    a. Summary:
        i. Mrs. Tinlin initially presented as a 41year old on 5/4/05 with DVT and PE. She had a history of difficulty maintaining adequate anticoagulation on Coumadin and had a significant positive family history of blood clots. It was determined that she should receive a retrievable IVC filter.
        ii. On 5/7/05, Mrs. Tinlin had a Bard Recovery filter placed. Cavogram reports a "rather prominent in transverse diameter IVC". "Which was at the upper limits of size for recovery filter". Filter was deployed in an appropriate infrarenal location.
        iii. Immediately following filter placement, the patient developed severe and increasing low back pain radiating down her left leg.
        iv. CT of Lumbar spine from 5/9/05 demonstrated "a few of the tines are adjacent to the anterior aspect of the pre-vertebral portion of the lumbar spine"
        v. Mrs. Tinlin continued to have complaints of leg pain resulting in an ED visit on 7/27/05.
        vi. 12/12/05 Vascular consultation for filter removal was performed. The patient was found to have a coagulopathy, so the decision was made to leave the filter in as she was told "it could be left in permanently".

vii. 1/27/06 Patient sustained a fall with onset of low back pain and worsening of leg pain. CT was negative for fracture. Patient had ESI and was discharged.
viii. 2/10/06 PCP visit for ongoing low back pain and radiating pain down legs.
ix. 2/15/06 PCP visit for ongoing low back pain and radiating pain down legs.
x. 4/11/06 PCP visit for ongoing low back pain and radiating pain down legs.
xi. 5/1/06 Call to PCP for ongoing low back pain and radiating pain down legs.
xii. 11/3/06 Call to PCP for chest pain and shortness of breath with lightheadedness and dizziness.
xiii. 3/28/07 Pain management consult. Continued complaints of low back pain.
xiv. 7/10/07 Pain management consult. Continued complaints of low back pain. Diagnosed with facet disease.
xv. 7/07 – 9/09 Multiple visits to spine specialists and neurologists for low back pain, and neurologic issues.
xvi. 3/24/10 Pain management. RFA Lumbar performed.
xvii. 5/31/11 PCP visit. Still with chronic low back pain.
xviii. 6/10/13 ED visit. Patient presented to the ED in significant distress with chest pain and hypotension. Found to have hemo-pericardium with cardiac tamponade related to perforated right ventricle secondary to fractured, embolized arm of filter. In addition, patient was diagnosed with cardiogenic shock and multi-organ system failure.
    1. She had immediate drainage of her pericardial effusion with drain placement and removal of 600 ml of bloody effusion.
    2. CTA of the chest demonstrated 2 fractured, embolized arms in the right ventricle. One arm had perforated the right ventricular wall and the other had penetrated the interventricular septum.
    3. The patient had a difficult post-procedural course complicated by pleural effusions, pulmonary edema, multi-system organ failure, and mental status changes.
    4. She was eventually discharged on 6/19/13.
    5. IR did not feel a new IVC filter was indicated and did not remove the current filter.

xix. 7/1/13 Hematology consult. Patient was restarted on anti-coagulation. Filter was left in place.

xx. 7/3/13 – 7/10/13 Cardiothoracic surgery consults.
    1. Superficial cellulitis of wound.
    2. No recommendation about removal of embolized arms.

xxi. 7/26/13 Cardiothoracic surgery consult.
    1. Confirmed presence of 2 fractured, embolized arms in right ventricle.
    2. Because of the risk of further migration, open cardiothoracic surgery with sternotomy and cardiopulmonary bypass was recommended for removal.

xxii. 7/30/13 – 8/9/13 Open cardiothoracic surgery with cardiopulmonary bypass.
    1. Median sternotomy with cardiopulmonary bypass.
    2. Removal of embolized arm from right ventricle.
    3. The second embolized arm could not be located.
    4. They performed complete arrest, and the left ventricle was explored, but the arm could not be located.
    5. The patient was closed.
    6. She was eventually discharged to a rehab facility on 8/7/13.
    7. She was then discharged to a sub-acute care facility on 8/9/13.

xxiii. 8/22/13 ER visit. Worsening back pain and right sided chest pain. Work-up negative.

xxiv. 11/13/13 CT surgery consult.
    1. Patient having issues with sternal wound healing. Moderate chronic pain.
    2. CT showed continued healing sternal wound.

xxv. 11/23/13 CT surgery consult.
    1. Continued sharp pain at sternum. Lasting 20 seconds with movement.
    2. CT confirms early sternal non-union.
    3. Patient counseled to decrease activities that precipitate the pain.

xxvi. 1/13/14 Pulmonary consult.
    1. Chronic cough and wheezing.
    2. Physician concerned about tracheal stenosis related to prior intubation.

xxvii. 2/3/14 Bronchoscopy.

1. Demonstrates some tracheomalacia.

xxviii. 3/27/14 CT surgery consult.
1. Patient still with sternal pain.
2. CT demonstrates that sternum is still not yet completely united.

xxix. 6/19/14 Cardiology consult.
1. Complaints of chest pain and cough thought to be related to diagnosis of tracheomalacia from intubation.

xxx. 9/26/14 Pulmonary consult.
1. Ongoing cough. Diagnosed with mild tracheomalacia.

xxxi. 8/19/15 CT scan for upper abdominal pain.
1. CT demonstrates incisional hernia related to sternotomy.

xxxii. 9/16/15 – 9/21/15 Laparoscopic repair of incisional hernia and diaphragmatic hernia.
1. Abdominal wall hernia closed primarily.
2. Diaphragmatic hernia closed with mesh.

xxxiii. 12/3/15 CT surgery consult
1. Patient advised her sternum was unstable. XR shows right sternoclavicular joint hyper-extended and dislocated at sternum.
2. Patient told to limit her movement.

b. Reasonable expectations of physicians for medical devices and informed consent:

i. In the everyday practice of medicine, I along with my colleagues and implanting and treating physicians have expectations of medical device companies like CR Bard and Bard Peripheral Vascular (referred to collectively in this report as "Bard") when they design, test, manufacture, market, and sell medical devices. Fulfilling these expectations in their design, testing, manufacturing, warning, and marketing of IVC filters allows physicians to properly and completely obtain informed consent from their patients. Fulfillment of these expectations also allows physicians to select the appropriate IVC filter and make appropriate therapeutic decisions on behalf of their patients as to whether an IVC filter is indicated or considered as a therapeutic option, and whether to use or not use a particular type of IVC filter.

ii. Moreover, a patient has reasonable expectations on what he or she should know in the same or similar circumstances as a

reasonable patient who has been prescribed or has considered having an IVC filter implanted.

iii. Informed Consent:

1. The AMA Code of Medical Ethics - CHAPTER 2: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING, *2.1.1 Informed Consent* states: Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should: (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about: (i) the diagnosis (when known); (ii) the nature and purpose of recommended interventions; (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.

https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics- chapter-2.pdf.

2. The AMA Code of Medical Ethics' Opinion 8.08 – Informed Consent states: The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts

> accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information (see Opinion 8.122, "Withholding Information from Patients").
>
> Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate.

http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.

I have adopted the above AMA Codes in my daily practice and, in my opinion, they represent the standard of care relative to Informed Consent, Patient Communication, and Decision-Making.

c. Failure to notify:
    i. Given the above responsibilities of a medical device manufacturer to the patient and the physician, and the physician to the patient, it is my opinion that Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates of fracture, embolization of fractured components, penetration, migration, including the known risk of death associated with the Recovery® filter in comparison to the original predicate device, the Simon Nitinol Filter®, and competitor filters. Instead, Bard continued to represent its filters as having superior safety, quality, and performance.

ii. Physicians and patients have expectations of medical device manufacturers which Bard failed to achieve.
    1. Physicians and patients expect Bard to produce a safe, and effective device that accomplishes the intended purpose with the lowest possible risk to the patient.

    2. Physicians and patients expect Bard to appropriately test the medical device prior to release using bench testing and clinical studies to produce unbiased information that is relevant to the device and its intended use.

    3. Physicians and patients expect Bard to use reasonable care in designing and producing a product that is not unreasonably dangerous and provides additional benefit over prior similar devices.

    4. Physicians and patients expect that, when Bard has marketed and sold an IVC filter as being a "permanent" filter, even with the additional benefit of potential retrieval, Bard has adequately and appropriately designed and tested the filter to be safe and effective for implantation as a permanent device.

    5. Physicians and patients expect that, when Bard has marketed an IVC filter as being a "permanent" IVC filter with the additional benefit of potential retrieval that the filter will have the same risk profile (in terms of type, likelihood, frequency, and severity) as other permanent IVC filters in the absence of some warning or explanation that the risk profile for the new device is actually different.

    6. Physicians and patients expect Bard to provide product warnings that clearly identify the dangerous aspects of the product.
        a. These warnings must be adequately:
            i. Clear
            ii. Accurate
            iii. Consistent

iv. Convey the likelihood, frequency, and severity of the risks involved with using the device

7. Physicians and patients expect Bard to have a reasonable program of surveillance for unexpected outcomes or complications and warn physicians of these complications when they arise.

iii. There were multiple safety signals with the Recovery filter. These signals came from MAUDE adverse event reports (79, 80, 81) (BPVE-01-0542150-53, BPVE-01-00526477). From reports in the medical literature (3, 13, 14, 28, 29, 33, 54, 56, 75, 78, 79), and from Bard's own internal risk analyses and documents (Bard HHE 12/17/04, BPVE-01-01019821-25, Jan. 2005 RAP, BPVE-01-01019773, G2 and G2X Fracture Analysis, 11/30/08, BPVE-01-01752823, Wong Filters Complaint History PPT 7/31/07, BPV-17-01-00170083, BPV-17-01-00035618-30).

iv. Despite the above warning signs that the Recovery filter had significant issues with safety, Bard continued to market the device for both permanent and retrievable indications in the prevention of PE from DVT (Recovery brochure, BPV-17-01-00007760 to 00007760, BPVE-01-00307678, BPVE-01-00201987). During this time, Bard acknowledged design flaws that needed to be corrected (BPVE-01-00373887, BPV-17-01-00165419-22, BPVE-01-00435296-5303) but instead chose to inappropriately utilize the data from the Grassi paper (24), and ignore their in-house studies, risk analysis, and the current medical literature, to justify the high complication rates and continued marketing practices. In addition, Bard embarked on a directed marketing plan to mitigate the damage of multiple early complications and deaths by deceiving operating physicians and training their representatives to place a "spin" and attempt to minimize the mounting evidence of significant and dangerous device malfunction (BPVE-01-00033810-24). Bard also held back information from its representatives for the same reason. (Timothy Fischer Depo., Mar. 29, 2017, at 111-112, 166, 168-169, 216-218, 224-225, 281-282.) In essence,

Bard chose to keep the product on the market until a new product was released rather than focusing on its duty to remove unsafe devices from the market.

v. The Bard Recovery IFU was inadequate for use by physicians in medical decision making and consent of the patient.
    1. The IFU describes a myriad of possible risks following IVC filter placement, listing every possible risk known to physicians without providing clear information on the likelihood of those risks or the potential severity of new complications such as, for example, fragment embolization.

    2. The IFU lists 15 potential complications or adverse events, diluting out any important warning that could be obtained from the document. The SNF (the Recovery's predicate device) IFU lists 4.

    3. The IFU provides no clear recommendations for imaging follow-up of the device.

    4. The IFU provides insufficient warning of the incidence and seriousness of the cascade of events of tilt, migration, fracture, and especially fractured component embolization to the heart and lungs that was characteristic of these devices and occurred with a higher frequency and more serious complications than the predicate SNF device and other permanent filters available at the time (3, 13, 14, 28, 29, 33, 54, 56, 75, 78, 79).

    5. Despite knowing that the Bard retrievable filters were not designed or tested for permanent use, the IFU provides no timeline for removal of the device, claiming that the device is safe and appropriate for both temporary and permanent use.

vi. Bard elected to not perform additional studies to further evaluate the safety, effectiveness, and durability of their filters. Instead, it embarked on a long-term plan to evolve its filter

through multiple generations while making small incremental changes to each generation in response to the safety issues that were arising in real time in patients that were unknowingly participating in a decade-long open experiment with Bard retrievable filters (BPVE-01-00008821, BPVE-01-002689911-13).

vii. Had I been Mrs. Tinlin's implanting physician and aware of the safety issues that were known to Bard at the time of implantation of this device, I would not have used the Recovery filter for the prevention of PE in my patients. I would have also advised my partners and colleagues not to use that filter. It is my opinion that Bard did not adequately warn physicians, including Mrs. Tinlin's implanting physician, of important safety risks and issues associated with its "retrievable" filters of which it was aware.

d. Failure of the Bard Recovery® Filter in Debra Tinlin:
   i. Debra Tinlin needed protection from the sequelae of possible DVT and PE. Thus, she needed a caval filtration device that could safely and effectively provide protection. Bard represented the Recovery® IVC filter as a device that could be safely placed permanently or temporarily, provide effective protection from PE, and then could be easily removed percutaneously without any time limitation. Given this backdrop, I render the following opinions:
      1. At the time of implantation, the risks associated with the Bard Recovery filter exceeded the alleged benefits to Mrs. Tinlin who needed safe and effective protection against DVT and PE.

      2. Mrs. Tinlin's Recovery filter failed to perform as a reasonable physician and/or patient would expect in that the filter has had multiple modes of failure including (a) tilt, (b) migration, (c) penetration of the IVC with interaction with the lumbar spine, aorta, duodenum, and the retroperitoneum, and (d) multiple arms of the filter fractured and migrated/embolized to the heart and pulmonary arteries. One of the migrated/embolized arms perforated the right ventricle resulting in bleeding into

the pericardial sac (hemopericardium), and cardiac tamponade. This resulted in an acute life-threatening situation that included severe hypotension, and multi-organ system failure. The second embolized arm perforated the interventricular septum of the heart between the right and left ventricles. The patient needed emergent open cardiothoracic surgery to remove the embolized arms from the right ventricle. The first arm was removed from the right ventricle apex and required multiple sutures to repair the defect. The second arm could not be located during surgery despite complete cardiovascular arrest and exploratory surgery of the left ventricle.

3. Mrs. Tinlin has experienced significant morbidity related to the open cardiothoracic surgery to remove the embolized arm of the filter from her heart. She experiences chronic chest pain due to non-union of her sternotomy, and dislocation of her right sternoclavicular joint. She has a chronic cough and exacerbation of her asthma related to tracheomalacia from intubation for the procedure. She has had to have multiple subsequent procedures for treatment of a diaphragmatic and anterior abdominal wall hernia following her sternotomy. There is a risk that the hernia could recur.

4. In addition to the embolized arms to the heart, Mrs. Tinlin has three arms that have embolized to the right lung. The future behavior and possible morbidity and mortality of these embolized arms is currently unknown. Similar fragments in the pulmonary system have resulted in chronic pain, pneumothorax/collapse of the lung, abscess, and hemorrhage into the lung. These embolized arms are in locations that are not amenable to percutaneous retrieval, and if they become symptomatic will require lung resection for removal. At the least, they will require life-long follow-up with CT imaging to document their stability.

5. The filter in the IVC has multiple legs that are interacting with or have penetrated nearby organs and structures. Most importantly, there has been chronic penetration of the L3 vertebral body, and interaction with the L3/L4 intervertebral disc for multiple years. This almost certainly contributed to the patient's multiple chronic complaints of low back pain and radiculopathy resulting in chronic pain management using narcotics.

6. The Bard Recovery IVC filter is unstable and is causing the patient multiple issues and symptoms and will need removal using advanced endovascular techniques that will require referral to a specialist in complex removal of these devices.

4. Bases of opinions:
   a. My opinions are based on the reasonable expectations that I and other similarly situated physicians have in regards to the responsibilities of a medical device manufacturer for the design, marketing, sales, and performance of their medical devices.

   b. My opinions are based on my systematic review of scientific and medical literature, the materials and medical records/films in this case, Bard internal documents, depositions, expert reports, and my clinical experience, education, and training. I personally performed the medical literature research and review. All articles were reviewed in a standardized fashion according my training as a physician and researcher and according to the standards set forth for medical professionals by the National Health and Medical Research Council (see Appendix).

   c. In trial or deposition testimony, I reserve the right to use examples of IVC filter devices including the SNF, Greenfield filter, Recovery filter, G2 filter, G2X filter, and the Eclipse filter.

   d. In trial or deposition testimony, I intend to use the images attached in this report under "Imaging Appendix" to demonstrate to the jury the position, condition, location of the filter and its components/fragments in relation to the patient's anatomy. I reserve the right to annotate the

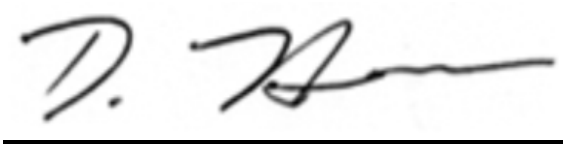
images during testimony to illustrate the testimony and opinions given above.

e. I reserve the right to use any additional images described above that were reviewed in this case as I see fit to illustrate the testimony and opinions given above.

f. In rendering my opinions in this matter, I took into consideration Mrs. Tinlin's co-morbidities, medical history, and preexisting problems.

g. All of my opinions are to a reasonable degree of medical and scientific certainty.

h. I understand that discovery is ongoing in this case. There may be additional information in the form of medical literature, expert reports, depositions, and case material. I specifically understand that certain of Mrs. Tinlin's treating physicians remain to be deposed. I reserve the right to supplement or to amend my opinions based on that discovery or if further pertinent information is discovered/obtained.



Darren R. Hurst, M. D. 12/7/18